



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,168	08/02/2006	Hirotochi Adachi	MUR-049-USA-PCT	5164
27955	7590	09/09/2010	EXAMINER	
TOWNSEND & BANTA c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402			DICKINSON, PAUL W	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			09/09/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,168	<b>Applicant(s)</b> ADACHI ET AL.	
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's arguments, filed 6/17/2010, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***New Grounds of Rejection***

##### ***Claim Objections***

Claims 1-6 and 8-17 are objected to because of the following informalities:  
Polylactic acid (i.e. polyactic acid) is misspelled. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112, New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification and original claims do not support the limitation "the distance between a particular projection and its corresponding

Art Unit: 1618

opening is smaller than the distance between the particular projection and an opening that does not correspond thereto". This limitation is not explicitly stated in the specification and original claims. Nor is it disclosed implicitly through a representative number of examples. Accordingly, the application fails to support this limitation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1618

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2002032480 (WO '480; document already in record) in view of US 20060222723 ('723). WO '480 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged pyramidal projections capable of piercing the skin and a plurality of through-holes (i.e. openings) capable of delivering a drug which are respectively arranged in correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 14, line 30 to page 15, line 7; page 18, line 11 to page 20, line 4; figures 3 to 4). The flat plate is not made of polylactic acid. Except for the material that the flat plate is made out of, the interface of WO '480 satisfies instant claim 1. The limitation in instant claim 1 that "the distance between a particular projection and its corresponding opening is smaller than the distance between the particular projection and an opening that does not correspond thereto" does not distinguish the interface of WO '480 from the instant invention. Assigning what projections "correspond" to what openings is completely arbitrary. Figure 17 of WO '480 is reproduced below:

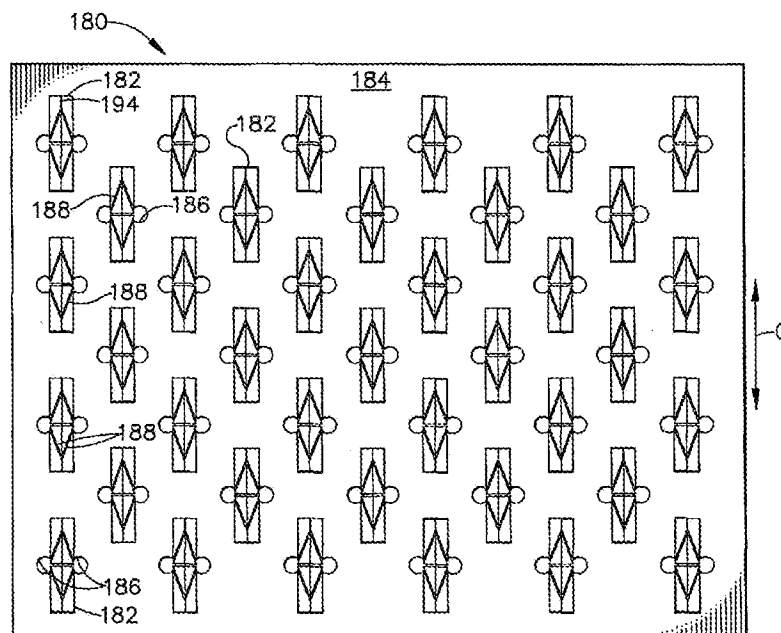


FIG. 17

194

There is no reason to say, for example, that the projection at the left most bottom “corresponds” to the nearest openings also at the left most bottom. It is equally valid to say that the projection at the left most bottom “corresponds” to the openings located at the upper most right. Accordingly, the interface of WO '480 meets the limitation that “the distance between a particular projection and its corresponding opening is smaller than the distance between the particular projection and an opening that does not correspond thereto.”

Channels for directing a drug from the openings to their corresponding projections are provided between the openings and their corresponding projections on the flat plate (see page 18, line 11 to page 20, line 4). Except for the material used, this satisfies instant claim 2. The ratio of openings and projections may be 1:1 (see Figure

Art Unit: 1618

13). Except for the material used, this satisfies instant claims 6 and 14. WO '480 discloses an interface for a transdermal drug administration device having a flat plate comprising a plurality of two-dimensionally arranged pyramidal projections capable of piercing the skin and a plurality of through-holes (i.e. openings) capable of delivering a drug which are respectively arranged in correspondence with the projections, wherein the openings are respectively arranged in proximity to their corresponding projections (see abstract; page 14, line 30 to page 15, line 7; page 18, line 11 to page 20, line 4; figures 3 to 4). This satisfies instant claim 1. Channels for directing a drug from the opening to their corresponding projections are provided between the openings and their corresponding projections on the flat plate (see page 18, line 11 to page 20, line 4). This satisfies instant claim 2. The ratio of openings and projections may be 1:1 (see Figure 13). This satisfies instant claims 6 and 14-17. The dimensions of the pyramidal projections and openings are result effective parameters in providing an interface that pierces the skin and efficacious delivery of the drug (see page 11, first full paragraph; page 14, second full paragraph to page 15 first paragraph). The pyramidal projections can have a vertical height of between 1 to 1000 microns, and a projection angle, relative to the flat plate, of from about 30° to about 90° (see pages 12-13, bridging paragraph; page 14, third full paragraph). This information allows one to calculate the diameters possible for the base of the pyramidal projection. For illustrative purposes only, when the height is 1000 microns and the projection angle is 60°, the diameter at the base of the pyramid would be about 116 microns (calculated from  $116 = 2 \cdot [1000 / \tan 60]$ ).

WO '480 fails to teach manufacturing the flat plate from polylactic acid. WO '480 further fails to disclose the pyramidal projection diameters, conical projection heights, and opening diameters disclosed in instant claims 3-5 and 8-13.

'723 discloses that polylactic acid is a common material used to make transdermal patches for local administration of a drug (paragraphs 172-179 and claim 19).

It would have been obvious to prepare the transdermal interface of WO '480 from polylactic acid. This material is commonly used in the art to prepare transdermal patches. If any part of the patch accidentally enters the body, such a broken projection, those parts will be safely absorbed by the body. It would have been further obvious to optimize the conical projection diameters, conical projection heights, and opening diameters to improve the lancing ability of the pyramidal projections and the percutaneous delivery of the drug. In this way, one would find the ranges given in the instant claims, through routine experimentation. WO '480 provides sufficient guidance to this end. '482 discloses projection heights of 1 to 1000 microns. This range fully encompasses Applicant's range of 100 to 700 microns. As illustrated above, the projection height and projection angles disclosed by WO '480 provide guidance to selecting appropriate base diameters, one such base diameter is 116 microns, which is encompassed by Applicant's range of 30 to 200 microns. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’ In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)” MPEP § 2144.05, II.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

September 8, 2010